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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,711	04/08/2004	Larry A. Gilbertson	MONS:140US	1699
46795 7590 09/07/2007 FULBRIGHT & JAWORSKI, L.L.P. 600 CONGRESS AVENUE, SUITE 2400 AUSTIN, TX 78701			EXAMINER KRUSE, DAVID H	
			ART UNIT 1638	PAPER NUMBER
			MAIL DATE 09/07/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/821,711

Applicant(s)

GILBERTSON ET AL.

Examiner

David H. Kruse

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 25 June 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 13 and 19-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12, 14-18 and 24-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **STATUS OF THE APPLICATION**

1. This Office action is in response to the Amendment and Remarks filed on 25 June 2007.
2. Those rejections or objections not specifically addressed in this Office action are withdrawn in view of Applicants' amendments.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Election/Restrictions***

4. Claims 13 and 19-23 remain withdrawn from further consideration pursuant to 37 CFR § 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 24 October 2006.
5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR § 1.48(b) and by the fee required under 37 CFR § 1.17(i).
6. The Examiner has required restriction between product and process claims. The Examiner considers pending claim 20 as directed to a process of using the elected product in the instant Application, and may be eligible for rejoinder if the elected invention is found to be allowable. Where applicant elects claims directed to the product, and a product claim is

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subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR § 1.116; amendments submitted after allowance are governed by 37 CFR § 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR § 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. §§ 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. § 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

***Claim Rejections - 35 USC § 103***

7. Claims 5-8, 12 and 14-18 remain rejected and claims 1-4, 9-11 and 24-226 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Heim *et al* (U.S. Patent Application Publication US 2003/0188345 A1, filed 28 June 2001) in view of Lange *et al* (U.S. Patent 5,939,539) and Ebinuma *et al* 1997 (Proc. Natl. Acad. Sci. USA 94: 2117-2121). This rejection is repeated for the reasons of record set forth in the previous Office action mailed 25 January 2007. Applicants' arguments filed 25 June 2007 have been fully considered but are not found to be persuasive.

Applicants teach that the problem to be solved by the claimed invention is that "The vector backbone DNA contains various plasmid maintenance genetic elements, e.g., origin of replications, bacterial selectable marker genes, and other DNA fragments not desirable in commercial crop products for regulatory issues." at page 2, lines 10-13 of the specification.

Heim *et al* teach that it is undesirable to introduce vector sequences, for example bacterial resistance genes also transferred into the genome of the plants in addition to the T-DNA with the desired transgenic nucleotide sequences (page 1, right column, 1<sup>st</sup> paragraph). Hence, the prior art had identified the same problem to be solved that has been asserted by Applicants' teachings.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the teachings of Heim *et al* to use other negative selectable marker genes in the DNA plasmid, such as those taught by others in the prior art; Lange *et al* or Hiroyasu *et al*. Given the success of those of ordinary skill in the art in expressing genes that can be used as a non-lethal negative selectable marker gene in transgenic plant, one would have a reasonable expectation of success. Heim *et al* were successful in distinguishing transgenic plants that incorporated DNA out side of the T-DNA, hence the DNA plasmid taught worked. Heim *et al* motivate those of ordinary skill in the art to use other selectable markers, including non-lethal negative selectable marker gene outside of the T-DNA.

Applicants argue that the claims are not rendered obvious by Helm *et al*. in view of Lange *et al*. and Ebinuma *et al*. because all elements of the claims have not been shown to be found in the art, and that Helm *et al*. do not teach a plant cell non-lethal negative selectable marker gene. Applicants argue that Lange *et al*. do not teach that the plant hormone degradative/modifying gene (gibberellin 20-oxidase) referred to can be used as a non-lethal negative selectable marker. Applicants argue that Lange *et al*. describe several uses for their invention for embodiments that both reduce and increase expression of the GA 20 oxidase gene, but that all of these uses relate to improving agronomic, horticultural, or plant breeding characteristics (page 8 2<sup>nd</sup> paragraph of the Response). In response to Applicants' arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208

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USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicants argue that Ebinuma et al. disclose the use of the *ipt* gene as a selectable marker, but only as a positive marker used in a very narrowly specialized selection system. Applicants argue that Ebinuma et al. is directed to a chimeric *ipt* gene that is entirely inserted into the transposable element Ac. Applicants' argue that Ebinuma et al. use *ipt* as a positive marker, thus selection is for expression of the gene as indicating positive transformation. Applicants argue that Ebinuma et al. do not teach the use of *ipt* as a non-lethal negative selectable marker gene, as found in Applicants claims (page 9, 1<sup>st</sup> paragraph of the Response). These arguments are not found to be persuasive because Ebinuma et al teach that use of the *ipt* produces loss of apical dominance and the suppression of root development in transformed plants thus it is easy to visually detect plant that have been transformed with the *ipt* gene (page 2117, right column). Hence, it would have been obvious to one of ordinary skill that substituting the *codA* gene taught by Heim et al with the *ipt* gene would produce a selectable phenotype if the *ipt* gene is incorporated during transformation. Applicants' recitation of "non-lethal negative selectable marker gene" is read as an intended use of a selection marker gene, which does not teach a non-obvious structure.

Applicants argue that the Specification explains in EXAMPLE 3 that the addition of the non-lethal selectable marker in the vector backbone had the unexpected effect of limiting the number of transgenic plants regenerated that have the backbone DNA and that the presence of the non-lethal negative selectable marker genes had the surprising

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effect of inhibiting regeneration of transgenic plants that contained the backbone sequences even before any screening for such plants took place, referring to the “non-lethal negative selectable marker genes”, *ipt* and *crtB*, provide exceptional [sic] reduction in the occurrence of transgenic plants with Ec.oriV DNA (paragraph spanning pages 9-10 of the Response). Applicants arguments concerning a teaching of unexpected results are not fully persuasive because the claims are directed a DNA plasmids comprising a “non-lethal negative selectable marker gene” much broader than Applicants’ asserted teachings of unexpected results. The Examiner notes that both the *crtB* and *ipt* genes used by Applicants involve modifying hormone production in transformed plants, gibberellins and cytokinins, respectively, but claim 1 is directed to subject matter much broader than Applicants’ asserted teaching of unexpected results.

Applicants argue that Applicants’ claimed invention yields the unexpected, beneficial property of substantially increasing the percentage of transformed plants without vector backbone DNA after a transformation event, without the need for exogenous substrates as required for conditional lethal markers, and without dependence upon another DNA integrating element such as Ac. Applicants argue that the addition of the non-lethal selectable marker in the vector backbone had the unexpected effect of increasing the percentage of single-copy transformants (page 10, 3<sup>rd</sup> and 4<sup>th</sup> paragraphs of the Response). These arguments are not found to be persuasive. See *In re Lindner*, 173 USPQ 356 (CCPA 1972) and *In re Grasselli*, 218 USPQ 769 (Fed. Cir. 1983) which teach that the evidence of nonobviousness should be commensurate with the scope of the claims.



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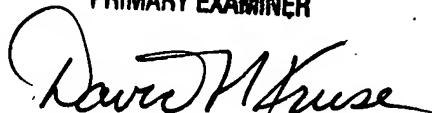
**Conclusion**

8. This office action is non-final in view of the new ground of rejection.
9. No claims are allowed.
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at (571) 272-0975. The central FAX number for official correspondence is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-1600.

DAVID H. KRUSE, PH.D.  
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read "David H. Kruse", written in a cursive style.

David H. Kruse, Ph.D.  
4 September 2007

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11. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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